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December 1, 2003

Office of Nutritional Products, Labeling, and Dietary Supplements Center for Food Safety and Applied Nutrition (HFS 800) Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

To Whom It May Concern:

I certify that the information contained in the enclosed notification, filed by Optigenex Inc. is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,

Richard Serbin, J.D., LL.M., R.Ph.

President and CEO

RS:pw

978 0162 LET 13445



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**USPS** Certified

Office of Nutritional Products, Labeling, and Dietary Supplements Center for Food Safety and Applied Nutrition (HFS 800) Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204



## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This notification is filed by Optigenex Inc., 750 Lexington Avenue, New York, NY 10022, pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6).

Name of Dietary Supplement

Activar<sup>TM</sup> AC-11<sup>TM</sup>

Name of Dietary Ingredient

Extract of Uncaria tomentosa, standardized

to 8% carboxy alkyl esters

Statements of Nutritional Support for the Dietary Ingredient

- supports natural DNA repair

- helps manage the effects of aging

- supports the body's natural ability to

repair and maintain its DNA

- supports the body's natural defenses

against the effects of aging

Pursuant to Food and Drug Administration regulation 21 C.F.R. § 101.93(a)(3), a signed certification is attached to this notice.

By: Richard Serbin, J.D. LL.M, R.Ph.

President and CEO, Optigenex Inc.

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## SUPPLEMENT FACTS

Serving Size: 2 Caplets

Servings Per Container: 30

Amount Per Serving DV

AC-11<sup>™</sup>

350 mg

Patented extract of Uncaria tomentosa, standardized to 8% Carboxy alkyl esters.

† DV (daily value) not established

Other ingredients: dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, steanc acid, magnesium stearate, silica and film coating (hydroxypropyl methylcellulose and polyethylene glycol).